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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/805,455	03/14/2001	Weiniu Gan	CL001165	9755

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EXAMINER
FREDMAN, JEFFREY NORMAN

ART UNIT	PAPER NUMBER
1637	5

DATE MAILED: 02/06/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/805,455	Applicant(s) GAN ET AL.	
	Examiner Jeffrey Fredman	Art Unit 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-23* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-2, 20, 21, drawn to proteins, classified in class 530, subclass 350.

II. Claim 3, drawn to antibodies, classified in class 530, subclass 387.1.

III. Claims 4-6, 8, 9, 22, 23, drawn to nucleic acids, vectors and host cells, classified in class 536, subclass 23.1.

IV. Claim 7, drawn to a transgenic non human animal, classified in class 800, subclass 2.

V. Claims 10-11, drawn to methods of making polypeptides, classified in class 435, subclass 69.1.

VI. Claim 12, drawn to methods for protein detection, classified in class 435, subclass 7.1.

VII. Claim 13, drawn to methods of nucleic acid detection, classified in class 435, subclass 6.

VIII. Claims 14-16, 19, drawn to methods of screening for modulators of protein, classified in class 436, subclass 501.

IX. Claim 17, drawn to pharmaceutical compositions, classified in class 514, subclass 1.

X. Claims 18, drawn to methods of treatment with a compound, classified in class 424, subclass 9.1.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions in Groups I, II, III, IV and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are unrelated because these represent structurally different chemical compositions which have different modes of operation, different functions and different effects. For example, the proteins of Group I function in binding or enzymatic activity within a cell while the antibodies of Group II function as detection agents, the nucleic acids of Group IIIfunction by hybridization for detection purposes, the transgenic animal results in a complete animal model for drug screening or other purposes and the pharmaceutical composition of Group IX is used for treatment of disease.

3. Inventions in Group I and in Group V are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the protein product can be made by expression as per Group V or by chemical synthesis.

4. Inventions in Group I and in Groups VI and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be

used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the protein can be used for detection purposes as in Group VI, for drug screening methods as in Group VIII or in protein purification methods such as the two hybrid systems.

5. Inventions in Group I and in Groups VII and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are unrelated because the protein does not function in the nucleic acid detection method of Group VII, and is not used in treatment as in Group X.

6. Inventions in Group II and in Group VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the antibody can be used for protein detection in the method of Group VI or can be used for protein purification methods.

7. Inventions in Group II and in Groups V, VII, VIII, X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions unrelated because the antibodies differ in operation, function and effects from the protein and nucleic acid

methods of Groups V, VII, VIII and treatment method of Group X since the antibodies are neither used nor made nor function in these methods.

8. Inventions in Group III and in Groups V and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the nucleic acid products of Group III can be used for the expression method of Group V, for the nucleic acid detection method of Group VII, for therapy methods or for nucleic acid purification methods..

9. Inventions in Groups III, V and VII and in Groups VI, VIII and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are unrelated because the nucleic acid and methods of protein expression and nucleic acid detection have different modes of operation and different effects than the protein detection, modulator screening method or treatment methods of Groups VI, VIII and X.

10. Inventions in Group IV and in Groups V-VIII and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are unrelated because the transgenic animal differs in operation, function and effects from the

synthesis methods of Groups V and VIII, the detection methods of Groups VI and VII and the treatment method of Group X.

11. Inventions in Groups V and VII and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are unrelated because the method of making polypeptides of Group V differs in mode of operation, function and effect from the detection method of Group VII or the compound of Group IX, with the result of Group V being protein made and the result of Group VII being nucleic acid detected and Group IX being a compound not used in either Group.

12. Inventions in Groups VI, VIII and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are unrelated because the protein detection method differs in operation, function and effect from the screening method of Group VIII and the treatment method of Group X, where Group VI results in detected protein, Group VIII results in an identified compound for treatment and Group X results in a treated patient.

13. Inventions in Group VI and VII and in Group IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are unrelated

because the detection methods of Group VI and VII do not use or make or relate to the compound of Group IX in operation, function or effect.

14. Inventions in Group VIII and IX are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the product of Group IX can be made chemically or by the method of Group VIII.

15. Inventions in Group IX and in Group X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product of Group IX can be used for treatment as in Group X, for use as a lead compound to identify improved versions of the pharmaceutical composition or for protein interaction or binding studies.

16. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

17. A telephone call was made to Justin Karjala on February 6, 2002 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

18. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Fredman whose telephone number is 703-308-6568. The examiner can normally be reached on 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

February 6, 2002

JEFFREY FREDMAN
PRIMARY EXAMINER